AUG - 9 2001

510(k) Summary K011320 1/3

1. Submitter Information:

1.1. Submitter:

Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, OH 44087
Phone: (847) 463-2001
FAX: (847) 463-2011

1.2. **Manufacturing Facility**:

Hitachi Medical Corporation
Kashiwa Works
2-1 Shintoyohuta, Kashiwa
Kashiwa City
Chiba Prefecture, Japan

1.3. Contact:
Robert H. McCarthy

1.4. Date: April 30, 2001

2. Device Name

2.1.	***Classification Name:***	Oximeter
	Classification Number:	74DQA
2.2.	***Trade/Proprietary Name:***	ETG-100
2.3.	***Predicate Device:***	Somanetics INVOS 3100A Cerebral Oximeter K960614

3. Device Description

3.1. Function

The ETG-100 is a device that uses near-infared spectroscopy for non-invasive mesurement of the relative levels of deoxy-hemoglobin and hemoglobin in the cerebral cortex.
An array of optical fibers mounted in a helmet is placed in contact with the scalp of the patient. Two wavelengths of near-infared light produced by laser diodes are transmitted through several of the optical fibers. The light passes through the scalp, skull and upper layer of the cerebral cortex. A very small quantity of light is reflected

back and is collected by optical fibers adjacent to the transmitting fiber. A baseline measurement is then taken. Measurements taken after the baseline measurement show relative changes in deoxy-hemoglobin and hemoglobin. These changes can be displayed in either a graphical form or as an image.
Optical encephalography is a way to measure the functioning of the brain by displaying a 2-dimentional image. The images are taken by measuring the change of blood in the surface area of the brain. The blood is measured by the near-infrared absorption by the Hemoglobin (Hb). The subject will experience no discomfort, as this is a non- invasive test, which is done by just contacting a small optical fiber tip on the surface of the scalp.
The exposure of the near-infrared is made from the surface of the skin using varying levels of near-infrared light. By utilizing the changes of light absorption, measurement of oxygenation and de-oxygenation of the Hemoglobin within the blood can be made at multiple points within the nearby surface area of the brain. Display, as a moving image is possible by reconstructing the distribution of blood flow changes of the surface area of the 2D topography images.
By this method, time changes of blood (volume) of various parts within the nearby surface area of the brain can be made into an image, which will provide data to measure brain functions.

4. Device Intended Use:

4.1. The intended use of the ETG-100 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

5. Device Technological Characteristics:

5.1. The characteristics of the ETG-100 Optical Topography system compare substantially with the INVOS 3100A predicate device, in both materials used, technology applied, and functional methodology. Differences of note do not affect safety and effectiveness of the device, intended use, or application methods. The device operates in a manner substantially equivalent to other cleared devices in this category, and performs as well as the predicate INVOS 3100A.

5.2. ***Biocompatibility***

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510(k) Summary

The ETG-100 is designed to comply with ISO10993-10 Biological Evaluation of Medical Devices: Test for Irritation and Sensitization.

5.3. Safety

The ETG-100 is a non-invasive device with no moving parts. It has been designed to comply with all applicable safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2001

Mr. Robert H. McCarthy
Director New Technology
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087

Re: K011320
Trade/Device Name: ETG-100
Regulation Number: 870.2700
Regulatory Class: II
Product Code: DQA
Dated: July 30, 2001
Received: July 31, 2001

Dear Mr. McCarthy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011320

Device Name: ETG-100

Indications for Use: The intended use of the ETG-100 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011320

Prescription Use ✓ OR Over-the-Counter Use _____